



Indiana State
Department of Health

Indiana Medical Error
Reporting System

Preliminary Report
for 2006

March 6, 2007

**Indiana State Department of Health
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This preliminary report was published by the Indiana State Department of Health (ISDH) on March 6, 2007 and may be found online at www.in.gov/isdh. For more information on this report contact:

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EXECUTIVE SUMMARY

On January 11, 2005, Indiana Governor Mitchell E. Daniels Jr. issued an Executive Order requiring the Indiana State Department of Health to develop and implement a medical error reporting system. The purpose of the reporting system was to obtain data that could be used towards reducing the frequency of medical errors, revealing the causes of medical errors, and empowering healthcare professionals to design methods to prevent or discover errors before patients are harmed.

This report is the first report of the Indiana Medical Error Reporting System. This is a preliminary report and presents information about reportable events occurring in Indiana health care facilities between January 1, 2006 and December 31, 2006. The report is based on data received by the Indiana State Department of Health prior to February 26, 2007. Because health care facilities have approximately six months to review events and report, additional reportable events for calendar year 2006 will likely be received in the coming months. The final report for 2006 will be released in August 2007 once complete 2006 data has been received.

Indiana's medical error reporting system is based on the National Quality Forum's twenty-seven serious reportable events. Only the most serious events are reportable events under this system. A serious event includes events resulting in death or serious disability or any event involving a wrong patient, body part, or procedure. Indiana is the second state to develop a medical error reporting system based on the National Quality Forum serious reportable events.

Requiring the reporting of these twenty-seven events is not meant as a way of identifying and punishing those responsible for the error. Studies have indicated that most medical errors are not the result of actions of individuals but rather the failure of the systems and processes used in providing healthcare. By reporting the most serious events, persistent problems can be identified and actions can be taken to prevent these events from occurring in the future. The requirement to report events encourages the movement towards increased awareness of patient safety issues and encourages work towards evidence-based initiatives to improve patient safety.

Indiana's Medical Error Reporting System requires that hospitals, ambulatory surgery centers, abortion clinics, and birthing centers report any reportable event as defined by the rules that occurs within that facility. The facility is required to report which of the twenty-seven reportable events occurred, the health care facility where the reportable event occurred, and the calendar quarter and year within which the event occurred.

For 2006, there were a total of 287 facilities required to report. Seventy-seven (77) reportable events were reported for 2006. Seventy-two (72) events occurred at hospitals while five (5) events occurred at ambulatory surgery centers.

Two reported events stand out as significant in the number of reports. There were twenty-three (23) reported events of stage 3 or 4 pressure ulcers acquired after admission to the facility. Twenty-three events represent approximately 1 event per 160,000 hospital discharges. The second most reported event was twenty-one (21) events of retention of a foreign object in a patient after surgery or other invasive procedure. Twenty-one events equates to 1 event per 81,000 surgical procedures.

The third most reported event was nine (9) events of surgery performed on the wrong body part. Nine events represent 1 event per 189,000 surgical procedures. Reported events are expected to increase in future reports as awareness of reporting requirements increases.

INTRODUCTION

This report is the first report of the Indiana Medical Error Reporting System. This is a preliminary report and presents information about reportable events occurring in Indiana health care facilities between January 1, 2006 and December 31, 2006. The report is based on data received by the Indiana State Department of Health prior to February 26, 2007. Because health care facilities have approximately six months to review events and report, additional reportable events for calendar year 2006 will likely be received in the coming months. The final report for 2006 will be released in August 2007 once complete 2006 data has been received.

The focus of this report is data that may be used to improve patient safety. Data on the number of medical errors and type of errors has not previously been gathered by the Indiana State Department of Health. This initial report therefore provides a baseline on the number of medical errors occurring in Indiana health care facilities. The initial data shows that stage 3 or stage 4 pressure ulcers acquired after admission to the hospital, retention of a foreign object in a patient after surgery, and surgery performed on the wrong body part are the three most common areas for medical error. The goal of the Indiana State Department of Health is that this data will increase focus on these issues and promote the development of evidence-based initiatives designed to improve patient safety.

Indiana has a tradition of excellence in healthcare. Indiana's health care facilities are among the most advanced in the country. Indiana colleges and universities are recognized leaders in healthcare education and research. Healthcare professionals are often recognized for the dedicated and outstanding care provided to Hoosiers. It is imperative that Indiana continue to lead the way in improving patient care and health outcomes. The reduction of medical errors is an important component of continuing the Hoosier tradition of quality healthcare.

The goal of this report is to improve healthcare services by focusing on data-driven initiatives. With the growth and technical advancement of the healthcare system, maintaining and improving patient safety has become a complex and long term process. Patient care today involves a large number of healthcare professionals and health care facilities. With this larger and decentralized system, there is an increased potential for medical errors. While individuals may, and do, make independent mistakes, medical errors are more often a system failure resulting from inconsistent care practices between professionals or facilities or communication lapses within or between the many health care professionals or facilities providing care to a patient.

The initial data on medical errors reinforces the need for health care facilities and providers to collaborate on quality. In today's healthcare system, patient care is generally not limited to a single provider or facility. The reduction of medical errors requires collaboration to promote consistent healthcare practices and ensure appropriate communication between providers. The medical error reporting system will hopefully encourage a culture in which health care providers report potentially unsafe situations without fear of reprisal in collaboration towards improved healthcare.

BACKGROUND ON MEDICAL ERROR REPORTING

History of Medical Error Reporting

Reports on medical errors can be traced back to the 1970's, when a physician-attorney named Don Mills analyzed more than 20,000 medical charts concluding that one patient in twenty was harmed by treatment.¹ A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Leape, and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality.²

The Institute of Medicine of the National Academy of Sciences

The Institute of Medicine was chartered in 1970 as a component of the National Academy of Sciences in Washington, DC. It is a nonprofit organization providing evidence-based analysis and guidance on matters of biomedical science, medicine, and health.³

In 1998 the Institute of Medicine appointed the Committee on the Quality of Health Care in America to identify strategies for achieving a substantial improvement in the quality of healthcare delivered to Americans. In 1999 the Institute of Medicine published a landmark report on medical errors entitled *To Err Is Human: Building a Safer Health Care System*.⁴ The report estimated that between 44,000 and 98,000 patients die each year as a result of medical errors. The report estimated that a medication error occurs for two of every one hundred patients admitted to a hospital. The report further estimated that the total cost of preventable medical errors to be between 17 and 29 billion dollars per year.⁵

The 1999 Institute of Medicine report significantly increased awareness of medical errors and brought attention to the need for reliable data on the number of medical errors occurring in health care facilities. A subsequent Institute of Medicine report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, reinforced the need for reliable data and cited the need for evidence-based policies and practices.⁶

The Institute of Medicine report cited several causes of medical errors including the following:⁷

- Lack of reliable data on the number of medical errors which limits the ability to identify origins of the problem and develop initiatives to resolve the problem

¹ D.H. Mills, *Medical Injury Information: A Preparation for Analysis and Implementation of Prevention Programs*, 236(4) *Journal of the American Medical Association*, pp. 379-381 (1976).

² Agency for Healthcare Research and Quality, *Medical Errors: The Scope of the Problem* (2000), Retrieved February 17, 2007 from <http://www.ahrq.gov/qual/errback.htm>.

³ Institute of Medicine of the National Academies, Retrieved February 12, 2007 from <http://www.iom.edu/CMS/AboutIOM.aspx>.

⁴ Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

⁵ *Id.*

⁶ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (National Academy Press, 2001).

⁷ Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

- Medical errors are often a system failure where care practices are inconsistent between healthcare professionals leading to mistakes
- With larger, decentralized, and fragmented health care facilities and an increase in the number of health professionals providing care to a patient, there is an increased potential for medical errors
- Access to patient information by health care providers
- Lack of legible handwriting or conversely data entry mistakes
- Use of acronyms or abbreviations
- Inadequate documentation
- Patient loads placed on staff resulting in timing issues in the delivery of care
- Competition between facilities resulting in the lack of development of communication systems between health care providers

The National Quality Forum

In a 1998 report, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposed creation of the National Quality Forum as part of an integrated national quality improvement agenda. The National Quality Forum was incorporated as a new organization in May 1999. The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.⁸

The National Quality Forum is a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting. The National Quality Forum, a public-private partnership, is made up of all parts of the healthcare system, including national, state, regional, and local groups representing consumers, public and private purchasers, employers, healthcare professionals, provider organizations, health plans, accrediting bodies, labor unions, supporting industries, and organizations involved in healthcare research or quality improvement.⁹

In 2002, the National Quality Forum published a report titled *Serious Reportable Events in Healthcare*. The report identified twenty-seven (27) events that are serious, largely preventable, and of concern to both the public and health care providers. The report recommended that these twenty-seven events be reported by all licensed health care facilities. The National Quality Forum suggested that analysis of reported events could provide caregivers and patients with important information about the safety of healthcare and opportunities for improvement.¹⁰

Indiana's Medical Error Reporting System is based on the National Quality Forum's twenty-seven serious reportable events. Indiana added language to clarify a few of the events and added definitions of terms to provide further clarification. Indiana is the second state to develop a medical error reporting system based on the National Quality Forum serious adverse reportable events. In 2003, Minnesota became the first state to institute a mandatory health event reporting system. Like Minnesota's system, the Indiana Medical Error Reporting System has been a collaborative effort with strong support from Indiana's healthcare community and a shared goal of improving patient safety.

⁸ National Quality Forum, <http://Qualityforum.org/about/mission.asp>.

⁹ *Id.*

¹⁰ *Serious Reportable Events in Healthcare*, National Quality Forum (2002).

Medical Error Reporting Systems

The National Academy for State Health Policy reported that, as of September 2005, twenty-four (24) states have passed legislation or regulations related to hospital reporting of adverse events. Twenty-three (23) are mandatory systems with one voluntary system. The National Academy reported that although the overriding reason for many of the reporting systems was to ensure accountability, many state reporting systems have a learning component.¹¹

The National Academy reported that the outcomes of reporting systems have varied. Reporting systems have the potential to improve patient safety through event report analysis and dissemination of best practices and lessons learned to prevent event recurrences. Some states send out safety alerts when incidents with significant consequences are reported. Other states attempt to aggregate data to identify patterns and trends across facilities. Newsletters highlight trends and showcase best practices to reduce incidents. Some states provide facilities with a comparison of their data with that of peer facilities or national standards. Other states produce routine reports showing trends in reportable events.¹²

Patient Safety and Quality Improvement Act of 2005

An emerging trend has been the development of patient safety centers. These centers are public or private entities that conduct activities designed to improve patient safety and the quality of healthcare delivery.

The Patient Safety and Quality Improvement Act of 2005 (109th Congress, 1st Session, Senate Bill 544) allows for certification of patient safety organizations that collect and analyze patient safety information for the purposes of encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk. Federal regulations enabling the certification of patient safety centers are pending. Additional information on these centers may be found in a report by the National Academy for State Health Policy.¹³

Patient safety centers have the potential to be important leaders in addressing medical errors and adverse events. Medical errors and adverse events are generally system-based problems. The solutions must also be system-based. Subject matter experts at Indiana colleges and universities are needed to study issues and develop evidence-based strategies for addressing care issues. Health policy organizations are needed to evaluate health care policies and develop best practices that promote consistent care practices between providers. Health provider associations are needed to coordinate information between providers and implement quality care initiatives. Patient safety centers serve the important role of coordinating these activities and ensuring that issues are addressed in a timely, evidence-based, and effective manner.

¹¹ Jill Rosenthal and Maureen Booth, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, National Academy for State Health Policy (October 2005), page 4.

¹² *Id.*

¹³ Jill Rosenthal and Maureen Booth, *State Patient Safety Centers: A new approach to promote patient safety*, National Academy for State Health Policy (October 2004).

INDIANA MEDICAL ERROR REPORTING INITIATIVE

Development of the Indiana Medical Error Reporting System

On January 11, 2005, Governor Mitchell E. Daniels Jr. issued Executive Order 05-10 requiring the Indiana State Department of Health to develop and implement a medical error reporting system. The Executive Order cited successfully implemented medical error report systems for reducing the frequency of medical errors, revealing the causes of medical errors, and empowering healthcare professionals to design methods to prevent or discover errors before patients are harmed.

Prior to 2006, the Indiana State Department of Health did not collect medical error data. The Indiana State Department of Health initiated development of a medical error reporting system and adopted rules requiring hospitals, ambulatory surgery centers, abortion clinics, and birthing centers to report medical errors. This Preliminary Report therefore contains the first data on medical errors occurring at Indiana health care facilities. The Indiana State Department of Health began collecting reportable event data on January 1, 2006. The data in this report covers the period from January 1, 2006 through December 31, 2006.

Purposes of the Medical Error Reporting Initiative

Purposes of reporting requirement:

- Increase awareness of the problem of medical errors
- Collect and analyze data on medical errors to determine whether there are areas where mistakes could be reduced
- Provide ability to analyze data to assist health care providers in reducing medical errors
- Provide information to patients so that they understand their role in helping to prevent errors
- Promote the sharing of successful solutions and improvements between health care providers
- Culture of open discussion. The goal is not to fix blame but to encourage reporting of errors so that initiatives may be developed to prevent mistakes
- Develop best practices aimed at reducing medical error
- Reduce healthcare costs through elimination of errors and duplication

Responsibility for quality care

One of the difficulties in reducing medical errors is overcoming the “culture of blame” that has permeated the healthcare system. This culture of blame has evolved in part as a result of intense competition between providers and efforts to avoid liability. By not communicating on quality issues, competing health care facilities have created inconsistent processes and procedures that have resulted in confusion among healthcare professionals as they move between facilities. This report is intended to begin development of a healthcare culture that looks beyond blame and supports patient safety through collaboration and responsibility.

Requiring the reporting of these twenty-seven events is not meant as a way of identifying and punishing those responsible for the event. Studies have indicated that most medical errors were not the result of actions of individuals but rather the failure of the systems and processes used in providing healthcare. By reporting the most serious events, persistent problems can be identified and

actions can be taken to prevent these events from occurring in the future. The requirement to report serious events encourages the movement towards increased awareness of patient safety issues and encourages work towards evidence-based initiatives to improve patient safety.

This report is not intended to place blame or focus attention on specific facilities or individuals. Such an approach would be counterproductive because the reality is that medical errors are usually the result of a system failure. A medical error that occurs in one facility may have actually begun in another facility. For instance, a pressure ulcer may have started in one long term care facility or hospital and increased in severity during a stay in another hospital. The event becomes a reportable event for the hospital if it reaches a stage 3 or 4 level while the patient is admitted to that hospital. The solution to this situation requires increased coordination and assessments by multiple health care providers. This illustrates the systemic nature of medical errors. Commercial manufacturers, health care facilities, clinics, healthcare professionals, professional organizations, government agencies, researchers, and patients all have responsibilities towards improving patient safety.

Healthcare licensing and certification surveys

The Indiana State Department of Health is the licensing authority for Indiana health care facilities. As part of the state licensing and federal certification program, the agency conducts regular health surveys at health care facilities. During the course of a survey, surveyors often review facts surrounding a possible medical error to determine whether there was a breach of health care facility regulations.

In developing the Indiana Medical Error Reporting System, one of the concerns of facilities was that a reportable event could be used to instigate a health survey of a health care facility. Such an action would likely discourage health care facilities from complete reporting as the reporting of an event could result in punitive action through the survey process. Incomplete reporting would reduce the reliability of the data and inhibit the development of quality of care initiatives. A goal of the system is to promote the reporting of events so that the data can be analyzed to determine areas where mistakes may be reduced.

To address this issue, the Indiana State Department of Health separated the Medical Error Reporting System from the health care facility survey program. The events reported by health care facilities via the Medical Error Reporting System are not received or reviewed by the health care surveyors. Events are reported through an online system that goes to the agency's health information and data program. Surveyors are not provided with the reported events and therefore cannot base their investigations on events reported by a health care facility through the Medical Error Reporting System.

The licensing and certification program regulations require the Indiana State Department of Health to investigate complaints concerning health care facilities. Surveyors will investigate any complaint received through the licensing and certification complaint system. Surveyors may therefore investigate potential reportable events discovered as part of existing standard survey procedures or as part of a complaint survey that is based on an event.

Survey process for determining whether events were reported as required

During the course of a survey at a health care facility, Indiana State Department of Health surveyors will review whether the facility has implemented a process for determining and reporting reportable events as required by state rule. The survey process is as follows:

- Surveyors will first review and determine whether the health care facility has an effective, organized, facility-wide, comprehensive quality assessment and improvement program as required by rule [see, for example, 410 IAC 15-1.4-2(a)].
- Surveyors will review and determine whether the health care facility has implemented a process for reporting to the Indiana State Department of Health each reportable event that is determined by the facility's quality assessment and improvement program to have occurred in the facility [see, for example, 410 IAC 15-1.4-2.2(a)(2) and 2.2(b)].
- Surveyors will review and determine whether reportable events identified by the facility's quality assessment and improvement program were reported in a timely manner [see, for example, 410 IAC 15-1.4-2.2(c)].
- Surveyors will review whether the facility took appropriate action to address the opportunities for improvement found through the facility's quality assessment and improvement program and whether the outcome of the action was documented as to its effectiveness, continued follow-up, and impact on patient care [see, for example, 410 IAC 15-1.4-2(b)].

If during the course of a survey surveyors become aware of an event that constitutes a reportable event, the surveyors will inform the Director of Acute Care who will verify that the reportable event was reported within the appropriate time requirements. The Indiana State Department of Health may take enforcement action if it finds that a health care facility failed to report a reportable event as required by the rule or failed to perform the actions described above.

OVERVIEW OF THE INDIANA MEDICAL ERROR REPORTING SYSTEM

Who is required to report?

Indiana rules (410 IAC 15-1.4-2.2, 410 IAC 15-2.4-2.2, 410 IAC 26, 410 IAC 27) require that hospitals, ambulatory surgery centers, abortion clinics, and birthing centers report events as defined in the rules. For 2006, there were a total of 287 facilities required to report.

What are the essential components of the reporting system?

The Indiana Medical Error Reporting System was organized based on several general principles. The following is a description of the general principles and how the reporting system addresses them:

- Preserve patient confidentiality. Identifying information about a patient is not reported to the Indiana State Department of Health. The only information reported is the category of event, the quarter in which the event occurred, and the facility in which the event occurred. The report does not include the quarter in which the event occurred to further limit the linking of an event with a patient. The inclusion of the quarter in the data is to assist facilities in identifying reported events to prevent duplication of reported events.
- Timely. Events are reported through an online system. The health care facility may review their reported events at any time throughout the year to ensure correct reporting. By having an online system with constant access, this allows the Indiana State Department of Health to assemble the data quickly at the end of the reporting period and produce a report. With six months to report events, health care facilities could report 2006 events as late as June 30, 2007. By having an online system with immediate access to the data, the Indiana State Department of Health expects to release its final 2006 report within a month or two of the end of the reporting period.
- Not punitive. The Indiana Medical Error Reporting System is intended to help find solutions to healthcare quality problems by promoting collaboration and communication between providers towards improving quality of care. As discussed above, information from reported events on the Indiana Medical Error Reporting System is not reviewed by surveyors as part of the survey process. The only punitive element is a failure to report reportable events.
- Data will be available on the internet and available to the public. Each year the Indiana State Department of Health will publish a report. The report will include the reported data for each health care facility. The report will be published on the Indiana State Department of Health Web site.
- Health care facilities to share best practices. The Indiana State Department of Health will be working with health care providers and associations to identify initiatives designed to provide solutions to events identified in the data. The Indiana State Department of Health will be including best practices in future reports.

What is the health care facility required to report?

The above health care facilities are required to report any reportable event as defined by the rules that occurs within that facility. Once a health care facility has determined that a reportable event has occurred it must send the Indiana State Department of Health the following information:

- (1) Which of the twenty-seven reportable events occurred;
- (2) The health care facility where the reportable event occurred; and
- (3) The quarter and calendar year within which the event occurred.

The facility submitting the reportable event is not to include any identifying information regarding:

- (1) a patient;
- (2) a licensed healthcare professional; or
- (3) a facility employee involved.

The facility submits the reportable event in an electronic format. The Indiana State Department of Health has established an internet portal system that allows a facility to register and then submit the required reports electronically. The system does not allow for the submission of information identifying a patient or healthcare professional.

What is not included in the Indiana Medical Error Reporting System?

The Indiana Medical Error Reporting System only collects data on the number and category of reported events. The Indiana System does not include the following:

- Specific information about the event. The health care facility only reports the category of the event. The facility does not provide the Indiana State Department of Health with a description of the event. The agency therefore does not have the ability to analyze each event. Each event must be reviewed by the facility's Quality Improvement and Assessment Program. The Indiana State Department of Health anticipates that patient safety centers will become an evaluator of reported events once those centers are developed.
- A way to distinguish between events that resulted in death and event resulting in serious disability. Reports to the Indiana Medical Error Reporting System do not distinguish between death and serious disability. Data reported does not reflect the number of deaths resulting from such events.
- Events that resulted in less than death or serious disability. The threshold for some events is an event resulting in death or serious disability. For those events, an event that occurs but results in no harm or injury or harm to a patient at less than death or serious disability are not reportable events.
- "Near misses." Near misses are events that were caught before the event occurred. For instance, the wrong patient is taken to the surgery department but it is caught before surgery is performed on the patient. The Indiana Medical Error Reporting System does not include near misses.

- Root cause analysis. Some states require a facility to perform a root cause analysis for each event and provide that analysis to the state department of health. Indiana's rule requires events to be reviewed by the facility's Quality Improvement and Assessment Program but does not require a report to the Indiana State Department of Health.

How does a health care facility determine whether a specific event is a reportable event?

Health care licensing rules require health care facilities to have an effective, organized, and comprehensive quality assessment and improvement program in which all areas of the facility participate (see, for example, 410 IAC 15-1.4-2). The facility is required to take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program. The Indiana Medical Error Reporting System requires the facility's quality assessment and improvement program to establish a process for reporting a reportable event that occurs within that facility.

The procedure for reporting a medical error is as follows:

- The health care facility must have a process in place for accurately and timely determining the occurrence of a potential reportable event
- When an event occurs that may constitute a reportable event, the event is referred to the health care facility's quality assessment and improvement program for review
- If the facility's quality assessment and improvement program determines that a reportable event occurred, the facility must report the event within fifteen days of the program's determination that a medical error occurred and not later than six months after the potential event is brought to the program's attention
- The reportable event is submitted to the Indiana State Department of Health via an online system. An individual is designated by each facility to report events and is provided access to the online system. The facility reports the category of the event and the quarter in which the event occurred.

What are the responsibilities of the health care facility towards correcting the medical error?

Health care licensing rules require health care facilities to have an effective, organized, and comprehensive quality assessment and improvement program in which all areas of the facility participate (see, for example, 410 IAC 15-1.4-2). The facility is required to take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program. The facility's quality assessment and improvement program is required to conduct in-depth analyses of events that may have been caused by medical error.

After conducting the analyses, the facility is required to develop and implement a plan to correct the problem. In developing corrective actions, the Indiana State Department of Health encourages collaboration between providers to develop consistent care practices that will reduce confusion and result in fewer medical errors. The Indiana Medical Error Reporting System is intended to promote the development of best practices that are shared across the provider community.

How will the Indiana State Department of Health enforce the reporting requirements?

The reporting requirements are included as part of the health care facility licensing rules. For violation of health care facility licensing rules, the Indiana State Department of Health may impose the following enforcement actions:

- issue a letter of correction
- issue a probationary license
- conduct a resurvey
- deny the renewal of the license
- revoke the license
- impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000) per violation

If the Indiana State Department of Health becomes aware that an event was not reported as required by rule, the agency will conduct an investigation. If the investigation determines that an event occurred and was not reported, the Indiana State Department of Health may issue an enforcement action.

What terminology is used in error reporting systems?

In preparing this report, the Indiana State Department of Health struggled with terminology to be used to describe these events. There is no accepted universal terminology for the events described in this report. A definition of applicable terms was not adopted during the rule promulgation process. In reviewing the issue, the Indiana State Department of Health found that a wide variety of terminology has been used to describe unexpected or unplanned events that result in injury to a patient.

The Joint Commission on the Accreditation of Healthcare Organizations encourages the voluntary reporting to the Commission of “sentinel events” and any root cause analysis performed by a hospital. The Joint Commission defines a sentinel event, root cause analysis, and near miss as follows:¹⁴

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response.

Root cause analysis is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. It progresses from special causes in clinical processes to common causes in organization processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such improvement opportunities exist.

¹⁴ Joint Commission on the Accreditation of Healthcare Organizations, *Sentinel events*, Comprehensive Accreditation Manual for Hospitals Update 4 (November 2004).

Near miss is used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a “near miss” falls within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.

The Minnesota annual report is called “Adverse Health Events in Minnesota.” Within the report, Minnesota used the terms “reportable events,” “reportable adverse health events,” “medication errors,” and “events.” Minnesota adopted the Joint Commission definition of an “adverse event” as follows:¹⁵

An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.

The Institute of Medicine defined the terms “error” and “adverse event” as follows:¹⁶

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a “preventable adverse event.” Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).

The National Patient Safety Foundation defined “healthcare error” as follows:¹⁷

An unintended healthcare outcome caused by a defect in the delivery of care to a patient. Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting.

Minnesota also adopted the Institute of Medicine’s definition of the term “patient safety” as follows:¹⁸

Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.

¹⁵ *Adverse Health Events in Minnesota, Second Annual Public Report*, at p. 73 (Minnesota Department of Health, February 2006).

¹⁶ Institute of Medicine, *To Err Is Human: Building A Safer Health System*, at p. 28 (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

¹⁷ National Patient Safety Foundation, http://www.npsf.org/html/about_npsf.html.

¹⁸ *Adverse Health Events in Minnesota, Second Annual Public Report*, at p. 73 (Minnesota Department of Health, February 2006). See also, Institute of Medicine, *To Err Is Human: Building a Safer Health System*, at p. 58 (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

The National Patient Safety Foundation defined “patient safety” as follows:¹⁹

The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.

While the term “serious adverse event” was used in a few instances in the Indiana State Department of Health rule, that term is at times misleading. The term “adverse event” is sometimes understood by healthcare professionals to mean an event in which there is a bad outcome that could not be prevented. Such a perception is inconsistent with the above definitions and the purposes of the Indiana Medical Error Reporting System. In addition, events such as criminal events or environmental events arguably do not fall under any definition of an “adverse event” or “medical error” because they do not arise from a medical procedure. Criminal events may be a facility management issue or an unpreventable incident.

The term “medical error” has increased in public recognition to represent a broad range of problems in a health care facility. In a study by the Kaiser Family Foundation, familiarity with the term “medical error” increased from 31% in 2004, to 43% in 2005, to 55% in 2006.²⁰ It was suggested to the Indiana State Department of Health that the agency not use the term “medical error” because it has a connotation of blame.

One of the desired outcomes of this data is to change the thinking of health care providers from associating a “medical error” with an individual action to approaching a medical error from the broader systemic perspective. Avoiding use of the term “medical error” hinders that goal because the medical error term has been widely accepted by the public and healthcare community to denote problems that occur in health care facilities. Many of the reportable events are consistent with the above definitions of error. For instance, operating on a wrong body part clearly fits the definition of an error. An error may be a result of systemic failure but it is still an error. Accepting responsibility requires health care facilities and providers to acknowledge that mistakes occur so it is important to use the term error where appropriate.

The Executive Order utilized the term “medical error” and referred to the system to be developed as the “Medical Error Reporting System.” The Indiana State Department of Health therefore continues to use those terms in reference to this system. Because the terms “medical error,” “serious adverse events,” and other terms are technically incorrect in some instances, the Indiana State Department of Health uses the more generic and appropriate term of “reportable events” or “reported events” to denote some of the events.

¹⁹ National Patient Safety Foundation, http://www.npsf.org/html/about_npsf.html.

²⁰ 2006 Update on Consumers' Views of Patient Safety and Quality Information, Kaiser Family Foundation / Agency for Healthcare Research and Quality (September 2006).

DEFINITIONS

The requirements for the Indiana Medical Error Reporting System are codified in the Indiana Administrative Code (IAC). The following are definitions used in the reporting system and are found at 410 IAC 15-1.1, 410 IAC 26-1, and 410 IAC 27-1.

"ASA Class I patient" means a normal, healthy patient.

"Biologics" means a biological product, such as:

- (1) a globulin;
 - (2) a serum;
 - (3) a vaccine;
 - (4) an antitoxin;
 - (5) blood; or
 - (6) an antigen;
- used in the prevention or treatment of disease.

"Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:

- (1) Fire.
- (2) Heat.
- (3) Chemicals.
- (4) Electricity.
- (5) Radiation.
- (6) Gases.

"Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so.

"Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate.

"Hypoglycemia" means a physiologic state in which:

- (1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
- (2) physiological or neurological, or both, dysfunction begins.

"Immediately postoperative" means within twenty-four (24) hours after either of the following:

- (1) Induction of anesthesia (if surgery or other invasive procedure is not completed).
- (2) Completion of surgery or other invasive procedure.

"Joint movement therapy" means all types of manual techniques, to include:

- (1) mobilization (movement of the spine or a joint within its physiologic range of motion);
 - (2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
 - (3) any other type of manual musculoskeletal therapy;
- regardless of their precise anatomic and physiologic focus or their discipline of origin.

"Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

“Low-risk pregnancy” means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:

- (1) Essential hypertension.
- (2) Renal disease.
- (3) Collagen-vascular disease.
- (4) Liver disease.
- (5) Preeclampsia.
- (6) Cardiovascular disease.
- (7) Placenta previa.
- (8) Multiple gestation.
- (9) Intrauterine growth retardation.
- (10) Smoking.
- (11) Pregnancy-induced hypertension.
- (12) Premature rupture of membranes.
- (13) Other previously documented condition that poses a high risk of pregnancy-related mortality.

“Neonates” means infants in the first twenty-eight (28) days of life.

“Serious disability” means either of the following:

- (1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
 - (A) not present on admission and requiring continued treatment; or
 - (B) for which there is a high probability of long-term or permanent lifestyle change at discharge.
- (2) Unintended loss of a body part.

“Sexual assault” means a crime included under IC 35-42-4 or IC 35-46-1-3.

“Surgery or other invasive procedure” means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. Such procedures include, but are not limited to:

- (1) Open or percutaneous surgical procedures.
- (2) Percutaneous aspiration.
- (3) Selected injections.
- (4) Biopsy.
- (5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
- (6) Laparoscopies.
- (7) Endoscopies.
- (8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters.

REPORTABLE EVENTS

The following are the twenty-seven (27) reportable events included in the Indiana Medical Error Reporting System.

SURGICAL EVENTS:

1. Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
 - (A) that occur in the course of surgery; or
 - (B) whose exigency precludes obtaining informed consent; or both.
2. Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
3. Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
 - (A) that occur in the course of surgery; or
 - (B) whose exigency precludes obtaining informed consent; or both.
4. Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
 - (A) Objects intentionally implanted as part of a planned intervention.
 - (B) Objects present before surgery that were intentionally retained.
 - (C) Retention of broken microneedles.
5. Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

PRODUCT OR DEVICE EVENTS:

6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility. Included are generally detectable contaminants in drugs, devices or biologics regardless of the source of contamination or product.
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:
 - (A) Catheters.
 - (B) Drains and other specialized tubes.
 - (C) Infusion pumps.
 - (D) Ventilators.
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the facility. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

PATIENT PROTECTION EVENTS:

9. Infant discharged to the wrong person.
10. Patient death or serious disability associated with patient elopement.
11. Patient suicide or attempted suicide resulting in serious disability, while being cared for in the facility, defined as events that result from patient actions after admission to the facility. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

CARE MANAGEMENT EVENTS:

12. Patient death or serious disability associated with a medication error, for example, errors involving the wrong:
 - (A) drug;
 - (B) dose;
 - (C) patient;
 - (D) time;
 - (E) rate;
 - (F) preparation; or
 - (G) route of administration.Excluded are reasonable differences in clinical judgment on drug selection and dose.
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the facility. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:
 - (A) Pulmonary or amniotic fluid embolism.
 - (B) Acute fatty liver of pregnancy
 - (C) Cardiomyopathy.
15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the facility.
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.
17. Stage 3 or Stage 4 pressure ulcers acquired after admission to the facility. Excluded is progression from State 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.
18. Patient death or serious disability due to joint movement therapy performed in the facility.

ENVIRONMENTAL EVENTS:

19. Patient death or serious disability associated with an electric shock while being cared for in the facility. Excluded are events involving planned treatment, such as electrical countershock.

20. Any incident in which a line designated for oxygen or another gas to be delivered to a patient:
 - (A) contains the wrong gas; or
 - (B) is contaminated by toxic substances.
21. Patient death or serious disability associated with a burn incurred from any source while being cared for in the facility.
22. Patient death associated with a fall while being cared for in the facility.
23. Patient death of serious disability associated with the use of restraints or bedrails while being cared for in the facility.

CRIMINAL EVENTS:

24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
25. Abduction of a patient of any age.
26. Sexual assault on a patient within or on the grounds of the facility.
27. Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the facility.

PRELIMINARY REPORT FOR 2006

Using this report

The best use of this report by consumers is as a guide for increasing awareness of patient safety issues. Informed consumers are better prepared to ask questions about issues that are important to them and contribute to achievement of their healthcare goals. By learning about patient safety issues, patients may be better able to communicate with their health care providers. If patients have questions or concerns about their medical care, patients should not hesitate in discussing these questions with their health care provider or facility and ask what he or she can do to assist in the prevention of medical errors.

This report provides information about best practices and activities that have been implemented by facilities and coalitions to improve patient safety. Patients should inquire of their health care facilities about possible consumer groups or activities that promote healthcare quality and patient safety. Collaboration of consumers with facilities is an important part of improving the quality of healthcare and many facilities have a wide variety of programs and resources designed to promote and improve public health. Links to healthcare quality organizations are provided at the end of this report. Many of these links provide information as to how patients can assist in ensuring their safety.

It is important to remember that this report should not be used to make comparisons of the safety or quality of the facilities. The number and type of reported events can vary based on factors other than differences in safety or quality of care, including:

- Size of the facility.
- The scope, complexity, and number of procedures performed at a facility.
- Interpretation differences of reportable events by each facility.

How to read this report

The data used in this Preliminary Report for 2006 is based on data received prior to February 26, 2007 and covers the reporting period of January 1, 2006 through December 31, 2006.

Health care facilities required to report are hospitals, ambulatory surgery centers, abortion clinics, and birthing centers. Tables are provided for each of the licensed facilities for these facility types in Appendices B through E. All licensed health care facilities in the above facility types that were open during 2006 are included in the Appendices.

Licensed health care facilities often include a wide range of services. A hospital, for instance, might include under their license a hospital, home health service, off-site clinics, and a long term care unit. Any reportable event occurring in any service included under a given license is reported under that license.

In some cases, hospitals have more than one hospital under one license. For instance, the license for Community Hospitals of Indiana includes both Community Hospital East and Community Hospital North. Any reportable event in either of the hospitals is reported under the Community Hospitals of Indiana license. The individual facility tables found in the appendices will indicate if there is more than one hospital included under that license.

Data for individual health care facilities

A table of reported events is provided for every Indiana health care facility that was required to report 2006 events. The table for each facility is located in the Appendices of this report. The individual tables are grouped according to the type of facility and the county of the facility. Appendix A is a summary of health care facilities that reported at least one event. Appendix B is the reported events for hospitals and begins with hospitals located in Adams County. Appendix C is the reported events for ambulatory surgery centers. Appendix D is the reported events for abortion clinics and Appendix E is the reported events for birthing centers.

Data on number of procedures performed at a facility

As a way of providing some comparative figures for hospitals and the reported events, the reports for individual hospitals found in Appendix B provide the number of persons discharged and the number of surgical procedures performed by each hospital. This data is provided in this report for the purpose of comparison of how many patients are treated and how many surgical procedures are performed by each hospital in relation to the number of errors reported. This data is required to be reported to the Indiana State Department of Health by hospitals no later than 120 days after the end of each calendar quarter. As a result, complete data from 2006 is not yet available. The data used is for the calendar year 2005 which is the latest complete year of hospital data available.

Similarly, for ambulatory surgery centers the number of surgical procedures performed at the facility is listed for each center. As explained above for the hospital data on discharges and surgical procedures, the most recent year of complete ambulatory surgery center data is 2005.

Combined Data for All Health Care Facilities

TABLE 1: Number of health care facilities included in this report

Type of Health Care Facility	Number of Facilities
Hospitals	139
Ambulatory Surgery Centers	137
Abortion Clinics	9
Birthing Centers	2
TOTAL	287

TABLE 2: Total number of reported events by type of health care facility

Type of Health Care Facility	Total Number of Reported Events
Hospitals	72
Ambulatory Surgery Centers	5
Abortion Clinics	0
Birthing Centers	0
TOTAL	77

TABLE 3: Total number of reported events by categories for all facilities combined

Category of Event	Number of Reported Events
Surgical	35
Product or Device	3
Patient Protection	0
Care Management	30
Environmental	6
Criminal	3
TOTAL	77

TABLE 4: Total number of health care facilities reporting one or more events

Type of Health Care Facility	Total Number of Facilities Reporting at Least One Event
Hospitals	36
Ambulatory Surgery Centers	5
Abortion Clinics	0
Birthing Centers	0
TOTAL	41

Combined Data for Hospitals

TABLE 5: Total reported events by hospitals by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		30
1. Surgery performed on the wrong body part	4	
2. Surgery performed on the wrong patient	2	
3. Wrong surgical procedure performed on a patient	3	
4. Retention of a foreign object in a patient after surgery	21	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		3
6. Death or serious disability associated with contaminated drugs, devices, or biologics	1	
7. Death or serious disability associated with misuse or malfunction of device	2	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		30
12. Death or serious disability associated with medication error	6	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	1	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	23	
18. Death or serious disability due to joint movement therapy	0	
ENVIRONMENTAL		6
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	2	
22. Death associated with a fall	4	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		3
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	2	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	1	
TOTAL NUMBER OF REPORTED EVENTS		72

Combined Data for Ambulatory Surgery Centers

TABLE 6: Total reported events by ambulatory surgery centers by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		5
1. Surgery performed on the wrong body part	5	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	0	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		5

Combined Data for Abortion Clinics

TABLE 7: Total reported events by abortion clinics by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		0
1. Surgery performed on the wrong body part	0	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	0	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		0

Combined Data for Birthing Centers

TABLE 8: Total reported events by birthing centers by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		0
1. Surgery performed on the wrong body part	0	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	0	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		0

ANALYSIS OF REPORTED EVENTS FOR 2006

Reported events by hospitals and ambulatory surgery centers

Seventy-seven (77) events were reported for 2006. Seventy-two (72) events occurred at a hospital while five (5) events occurred at an ambulatory surgery center. That data is consistent with the scope of the facilities. Because an ambulatory surgery center does not have overnight stays and performs limited services, many of the twenty-seven reporting categories would not be applicable to an ambulatory surgery center. For instance, pressure ulcer events would not occur at an ambulatory surgery center because the patient is not in that facility long enough to develop the pressure ulcer level required for reporting. Because pressure ulcers were the most reported event at hospitals, the unlikely occurrence of this event at an ambulatory surgery center significantly reduces the expected number of reported events at those facilities. The data is consistent with that expectation.

There are a few categories that theoretically would be as likely to occur at an ambulatory surgery center as at a hospital. Surgical events would fall into this category. In 2005, there were 1,220,929 reported surgical procedures performed at hospitals and 481,410 surgical procedures performed at ambulatory surgery centers. There were a comparable number of surgeries performed on the wrong body part between the two types of facilities. Four (4) wrong body part procedures were performed at hospitals and five (5) were performed at ambulatory surgery centers. Considering that ambulatory surgery centers perform only 28% of the surgical procedures, the rate for ambulatory surgery centers for this event is significantly higher than for hospitals.

There were significant differences between the two types of facilities on the other surgical events. Most significantly, hospitals reported twenty-one (21) events where a foreign object was retained in a patient after surgery. Ambulatory surgery centers reported no events in that category. Hospitals reported two (2) procedures performed on the wrong patient and three (3) wrong surgical procedures. Ambulatory surgery centers reported no events in those categories.

These discrepancies, particularly the differences with regard to foreign objects, warrant further study to determine why there are statistical differences. It would be informative to know whether the differences are solely related to the type of surgeries performed at the facilities or whether there are differences in practices at the facilities.

Thirty-six (36) hospitals and five (5) ambulatory surgery centers reported at least one reportable event. This represents 26% of hospitals and 4% of ambulatory surgery centers. For the same reason as discussed above, this is an expected result. Ambulatory surgery centers have a more limited scope and therefore would likely have fewer events to report.

In looking at the number of reported events by individual facilities, the licensing status of a health care facility likely is a consideration in analyzing the number of events occurring at a specific facility. Reports for individual facilities are by health care facility license. A facility may have more than one hospital under the license. One health care facility, Clarian Health Partners accounted for fifteen of the reported events. In analyzing that information it should be noted that Clarian includes several large hospitals and services under the Clarian Health Partners license. Any reportable events occurring at Methodist Hospital of Indianapolis, Indiana University Hospital, and Riley Hospital for Children are reported under that one license.

Reported events by abortion clinics and birthing centers

No reportable events were submitted by abortion clinics or birthing centers for calendar year 2006. Similar to ambulatory surgery centers, abortion clinics and birthing centers have limited services. Many of the twenty-seven reporting categories would not be applicable to an abortion clinic or birthing center. Because abortion clinics and birthing centers are limited in services and the scope is much smaller than even an ambulatory surgery center, the Indiana State Department of Health expected to have few, if any, reported events by these facilities. The data is consistent with that expectation as there were no reported events.

Analysis of reported events

Two reported events stand out as significant in the number of reports. There were twenty-three (23) reported events of stage 3 or 4 pressure ulcers acquired after admission to the facility. The second most reported event was twenty-one (21) events of retention of a foreign object in a patient after surgery or other invasive procedure. These two errors account for forty-four (44) of the seventy-seven (77) reported events or 57.1% of the reported events.

The third most reported event was surgery performed on the wrong body part. This event accounted for nine (9) of the seventy-seven (77) reported events. The fourth most reported event was death or serious disability associated with a medication error. Medication errors accounted for six (6) of the seventy-seven (77) reported events.

Table 9 lists the top four reported events and their frequency of occurrence. Based on reported 2005 data, there were a total of 1,702,339 surgical procedures performed in Indiana hospitals and ambulatory surgery centers. Based on reported 2005 data, there were 3,693,583 hospital discharges.

TABLE 9. Top Four Reported Events in Indiana for 2006

Event	Number of Reported Events	Percent of Total Number of Reportable Events	Ratio of Number of Reported Events to Total Number of Discharges or Surgical Procedures
Stage 3 or 4 pressure ulcers acquired after admission	23	29.9%	1 event per 160,000 discharges
Retention of foreign object in patient after surgery	21	27.3%	1 event per 81,000 surgical procedures
Surgery performed on the wrong body part	9	11.7%	1 event per 189,000 surgical procedures
Death or serious disability associated with medication error	6	7.8%	1 event per 615,000 discharges

In analyzing the categories of events, surgical events and care management events constituted sixty-five (65) of the seventy-seven (77) reported events or 84.4% of the reported events. Table 10 lists the percentage of the event categories.

TABLE 10. Percentage of Category of Events

Category of Event	Number of Reported Events	Percentage of all Reported Events
Surgical	35	45.4%
Product or Device	3	3.9%
Patient Protection	0	0
Care Management	30	39.0%
Environmental	6	7.8%
Criminal	3	3.9%
TOTAL	77	100%

Comparison with Minnesota data

Because this is the first report for Indiana, there are no previous years of data to which comparisons can be made. At least one other state may be useful for comparisons. In 2003 Minnesota became the first state to initiate mandatory adverse health event reporting using the National Quality Forum events. Minnesota's reportable events are essentially the same twenty-seven (27) events that are required to be reported in Indiana. In adopting rules, Indiana made slight revisions to a few items and added definitions for increased clarification. Minnesota has issued three Adverse Health Events in Minnesota Annual Reports.²¹ Minnesota's annual reports are available at their website.²²

Besides using the same National Quality Forum events, Indiana and Minnesota have a comparable number of hospitals and relatively comparable populations. As indicated in Table 11, Indiana and Minnesota have virtually the same number of licensed hospitals, 139 in Indiana and 137 in Minnesota. For 2006 Indiana had thirty-six (36) hospitals (25.9%) submitting reportable events. Minnesota's last reporting period shows forty (40) hospitals (29.2%) submitting reportable events.

²¹ Adverse Health Events in Minnesota Hospitals, First Annual Public Report (Minnesota Department of Health, January 2005); *Adverse Health Events in Minnesota, Second Annual Public Report* (Minnesota Department of Health, February 2006); *Adverse Health Events in Minnesota, Third Annual Public Report* (Minnesota Department of Health, January 2007).

²² Adverse Health Events in Minnesota: www.health.state.mn.us/patientsafety/publications/index.html

TABLE 11. Comparison of Indiana and Minnesota Population and Licensed Facilities

	Indiana	Minnesota
Population U. S. Census (2000)	6,080,485	4,919,479
Number of licensed hospitals	139	137
Number of licensed ambulatory surgery centers	137	46

Data between the two states is not exactly parallel. Minnesota's reporting year begins October 7 while Indiana's begins January 1. Both periods however cover a twelve month reporting period. Both Minnesota and Indiana reportable events come primarily from the categories of surgical events and care management events.

Table 12 shows that surgical and care management events are the most reported events in both states. Within those categories of events the specific events break down as follows:

TABLE 12. Comparison of Reports of Types of Events for Indiana and Minnesota

Type of Event	Indiana (1/1/2006-12/31/2006)	Minnesota (10/7/2005-10/6/2006)
Surgical	35	74
Products of Devices	3	4
Patient Protection	0	5
Care Management	30	55
Environmental	6	12
Criminal	3	4
Total	77	154

Table 13 shows the top four reported events in each state. The top four events are the same for each state and numbers of reports are ranked in the same order with stage 3 or 4 pressure ulcers the most reported event in each state. Minnesota reports that pressure ulcers and foreign objects retained after surgery comprise the most reported events and that fact is mirrored in other states that require reporting of similar reportable events.²³

²³ Adverse Health Events in Minnesota, Third Annual Report (January, 2007) by the Minnesota Department of Health, St. Paul, MN.

TABLE 13. Comparison of Top Four Reported Events in Indiana and Minnesota

Event	Indiana (1/1/2006-12/31/2006)	Minnesota (10/7/2005-10/6/2006)
Stage 3 or 4 pressure ulcers acquired after admission	23	48
Retention of foreign object in patient after surgery	21	42
Surgery performed on the wrong body part	9	23
Death or serious disability associated with medication error	6	6

Table 14. Minnesota Trends for Foreign Objects and Pressure Ulcers

Reporting Period	Hospitals Reporting	Foreign Objects	Pressure Ulcers	Total Reported Events
7/1/2003 to 10/06/2004	30	31	24	99
10/7/2004 to 10/06/2005	23	26	31	106
10/7/2005 to 10/06/2006	40	41	48	154

PATIENT SAFETY ACTIVITIES IN 2006

Numerous health care facilities and organizations conducted patient safety activities during 2006. The following are patient safety activities and initiatives conducted in 2006 known to the Indiana State Department of Health.

STATE AND FEDERAL QUALITY CARE INITIATIVES

CMS Hospital Quality Indicators

The Centers for Medicare and Medicaid Services (CMS) Hospital Quality Alliance (HQA) is a public-private collaboration that collects and reports hospital quality performance information. This effort is intended to make critical information about hospital performance accessible to the public and to inform and invigorate efforts to improve quality. Participating hospitals are voluntarily reporting the data. The goals are to promote the best medical practices associated with the targeted clinical disorders, prevent or reduce further instances of these selected clinical disorders, and prevent related complications.

The Hospital Quality Alliance developed quality measures for acute myocardial infarction (heart attack), heart failure, and pneumonia. In 2006, quality measures were added for surgical infection. Each measure represents a treatment that the health care provider should follow in treating the condition. Reporting of these quality measures is voluntary. The Indiana State Department of Health added these quality measures to its hospital consumer report. The hospital consumer reports may be found at <http://www.in.gov/isdh/regsvcs/acc/hosrpt/index.htm>.

PATIENT SAFETY INITIATIVES

National Patient Safety Foundation, *National Patient Safety Awareness Week*.

The National Patient Safety Foundation is an organization dedicated to improving the safety of patients. Each year the Foundation designates a Patient Safety Awareness Week. Patient Safety Awareness Week is a national education and awareness-building campaign for improving patient safety at the local level. Hospitals and healthcare organizations across the country are encouraged to plan events to promote patient safety within their own organizations. Educational activities are centered on educating patients on how to become involved in their own healthcare as well as working with hospitals to build partnerships with their patient community. The 2006 Patient Safety Awareness Week was March 6-10, 2006.²⁴

Institute for Healthcare Improvement - 100,000 Lives Campaign

In December 2004, the Institute for Healthcare Improvement, a Cambridge, Massachusetts based not-for-profit organization launched a national campaign to increase awareness and align improvement

²⁴ National Patient Safety Foundation, http://www.npsf.org/html/about_npsf.html.

efforts to prevent unnecessary deaths in hospitals. The efforts were based upon six specific interventions:²⁵

- Deploy rapid response teams at the first sign of patient decline
- Deliver reliable, evidence-based care for acute myocardial infarction to prevent deaths from heart attacks
- Prevent adverse drug events by implementing medication reconciliation
- Prevent central line infections by implementing medication reconciliation
- Prevent surgical site infections by reliably delivering the correct perioperative antibiotics at the proper time
- Prevent ventilator-associated pneumonia by implementing a series of interdependent, scientifically grounded steps

The Indiana Hospital & Health Association and the Indiana Patient Safety Center offered educational programs on all six of the Institute for Healthcare Improvement 100,000 Lives campaign interventions during 2005-2006. Ninety-three percent of Indiana's short term acute hospitals participated in this first stage of the campaign.

Institute for Healthcare Improvement - Protecting 5 Million Lives from Harm Campaign:

Building on the success of the Campaign to Save 100,000 Lives, the Institute for Healthcare Improvement launched the Campaign to Protect 5 Million Lives from Harm. This next phase of national campaign activity will reinforce the six interventions from the 100,000 Lives Campaign and add six new recommended interventions to prevent harm to patients to include:²⁶

- Preventing harm from high alert medications (including anticoagulants such as heparin and warfarin, narcotics, sedatives and insulin)
- Preventing pressure ulcers by reliably using science-based guidelines for their prevention
- Reducing surgical complications by reliably implementing all of the changes recommended by the Surgical Care Improvement Project (www.medqic.org/scip)
- Reducing Methicillin-Resistant *Staphylococcus Aureus* (MRSA) infections by reliably implementing scientifically proven infection control practices
- Delivering reliable, evidence-based care for congestive heart failure to avoid readmissions
- Getting boards of directors involved in quality and patient safety efforts.

The Indiana Patient Safety Center hosted the first regional launch event for the 5 Million Lives Campaign in Indianapolis on January 16, 2007, featuring national speakers and experts from Indiana. Almost 260 nurses, doctors and safety professionals attended this educational event focused on implementing the changes in their hospitals.

Healthcare Technical Assistance Program

Purdue University's Regenstrief Center for Healthcare Engineering provided short term consulting for Indiana Hospital & Health Association hospitals. Many of these projects focused on standardizing processes to improve system reliability and patient safety. Issues reviewed included:

²⁵ Protecting 5,000,000 Lives from Harm Campaign: www.ihl.org/IHI/Programs/Campaign

²⁶ Protecting 5,000,000 Lives from Harm Campaign: www.ihl.org/IHI/Programs/Campaign

- Patient flow in emergency department, operating room, labor and delivery, and medical surgical units
- Scheduling of operating room and other departments
- Pharmacy processes and medication safety
- Documentation and improvement of administrative functions
- Training on continuous improvement methods

Reducing Methicillin-Resistant *Staphylococcus Aureus* (MRSA)

The Indiana University Center for Health Services and Outcomes Research at the IU School of Medicine's Regenstrief Institute obtained a \$350,000 grant from the Agency for Healthcare Research and Quality to test techniques to reduce antibiotic resistant bacteria.

The AHRQ Accelerating Change and Transformation in Organizations and Networks is a five-year implementation model of field-based research that fosters public-private collaboration in rapid-cycle applied studies. This collaboration links with many of the nation's largest healthcare systems with top researchers to turn research into practice.

The purpose of the Indiana University Center for Health Services and Outcomes Research project is to measurably reduce hospital-acquired infections within selected acute care facilities or hospitals by fifty percent and document how this was done to help others achieve success in similar settings.

Improving care for patients with congestive heart failure

Health Care Excel, the Indiana Rural Health Association, and the American Heart Association joined forces in 2005-2006 to implement the Indiana Critical Access Hospital Heart Failure Pilot Program. The work was funded through a Small Hospital Improvement Grant and a grant from the Indiana State Department of Health to plan and implement the American Heart Association *Get With The Guidelines for Heart Failure* program in nine rural, critical access hospitals.

INDIANA PATIENT SAFETY ORGANIZATIONS

Indiana Patient Safety Center

The Indiana Patient Safety Center was formed on July 1, 2006 as a partnership among the Indiana Hospital & Health Association, Indiana State Medical Association, Health Care Excel (Indiana's federal contractor of Medicare quality improvement), Indiana University School of Medicine Regenstrief Institute Center for Health Services and Outcomes Research, and the Purdue University Regenstrief Center for Healthcare Engineering. The mission of the Indiana Patient Safety Center is to facilitate the development of safe and reliable healthcare systems that prevent harm to patients across Indiana.²⁷

²⁷ For information about the Indiana Patient Safety Center contact Betsy Lee, RN, MSPH, Director, Indiana Patient Safety Center, 1 American Square, Suite 1900, Indianapolis, IN 46282, 317/423-7795, blee@inhha.org, www.indianapatientssafety.org

Regional Patient Safety Coalitions

Regional patient safety coalitions exist or are emerging in different communities across the state. The Indianapolis Coalition for Patient Safety formed in 2003 as a vehicle for building collaborative patient safety work throughout the city. Over the past several years, the Indianapolis Coalition for Patient Safety has worked together to implement key interventions from the Institute for Healthcare Improvement Campaign to Save 100,000 Lives and the new Campaign to Protect 5 Million Lives from Harm. The Coalition has worked to standardize a city-wide list of “do not use” abbreviations. Such standardization helps reduce errors in medication ordering and interpretation. The Indianapolis Coalition is also working to establish a standardized surgical site verification policy and to address safety issues from high-risk medications, such as heparin and other anticoagulants.

Other coalitions have formed or are forming throughout the state. In the northern part of Indiana, the Michiana Patient Safety Coalition is collaborating to standardize the color of patient armbands among the various hospitals in the region to reduce confusion and the potential for error. In the southern part of Indiana, the Community Patient Safety Coalition of Evansville is coordinating patient safety activities in the tri-state area.

EDUCATIONAL PROGRAMS OFFERED IN 2006

Clarian Patient Safety Summit

Clarian Patient Safety Summit, Methodist Hospital, Indianapolis, March 9, 2006. As part of Patient Safety Week activities, Clarian Health Partners conducted an educational program on patient safety. Speakers provided information on patient safety and best practices.

Indiana Patient Safety Center Educational Briefing

Indiana Patient Safety Center, *Educational Briefing on Public Reporting of Adverse Events in Indiana*, Indianapolis, October 10, 2006. The Indiana Patient Safety Center conducted a one-day conference on adverse events. Presentations included representatives from the Minnesota Hospital Association discussing the Minnesota adverse event reporting initiatives and Minnesota initiatives on pressure ulcers. Representatives from Indiana hospitals presented Indiana hospital best practices on reducing pressure ulcers.

IUPUI Course on Quality and Patient Safety

A new inter-professional course was offered at Indiana University Purdue University at Indianapolis School of Public and Environmental Affairs for graduate-level learners in medicine, nursing, public health, informatics, health administration and other health-related disciplines. The course content includes an introduction to evidence-based quality and patient safety programs. The content and practical applications focus on the current science of patient safety and best practices, essential leadership skills, and techniques and tools for measurement and analysis. The course is taught by a team of faculty from the Indiana Patient Safety Center, the Indiana University Schools of Medicine and Nursing, and Purdue University Regenstrief Center for Healthcare Engineering. The course will be used as a model for a new Patient Safety Institute to be offered in Fall 2007 and coming years through the Indiana Patient Safety Center.

BEST PRACTICES

A goal of the Indiana Medical Error Reporting System is to promote the development of best practices directed at improving patient safety. In future years the agency hopes to report on best practices developed from patient safety initiatives. In this initial report, the Indiana State Department of Health provides best practices on what patients can do to help prevent medical errors. These best practices were adapted from best practices originally developed by the Agency for Health Quality and Research and included in the initial Minnesota Annual Report.²⁸

- Be an active member of your healthcare team.

Take part in every decision about your care, and don't be afraid to ask questions. Patients who are more involved with their care tend to get better results.

- Speak up if you have questions or concerns.

You have a right to question anyone who is involved with your care. Don't be embarrassed if you don't understand. It is your right to know what is happening.

If you feel that you are about to be given the wrong medication or treatment, or if something doesn't feel right, speak up. Ask a family member or friend to speak up for you if you can't.

- When you are being discharged, ask your doctor to explain the treatment plan you will use at home.

Learn about your medicines and find out when you can get back to your regular activities. Research shows that at discharge doctors think patients understand more than they really do about what they should or shouldn't do when they return home.

- Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.
- Ask for written materials related to your condition and to proposed treatments.

You can read information at home and think of questions to ask at your next doctor visit.

- Make sure that someone, such as your personal doctor, is in charge of your care.

This is especially important if you have many health problems or are in a hospital.

- Make sure all health professionals involved in your care have important health information about you.

Do not assume that everyone knows everything they need to know.

²⁸ *Adverse Health Events in Minnesota Hospitals, First Annual Public Report*, at p. 5 (Minnesota Department of Health, January 2005). See also, Agency for Health Quality and Research, Patient Fact Sheet: 10 Tips to Help Prevent Medical Errors Online, <http://www.ahrq.gov/consumer/> (January 2005).

RECOMMENDATIONS

This is a preliminary report of the Indiana Medical Error Reporting System. The Indiana State Department of Health collected data on the number of reported events and the category of the reported event. The Indiana State Department of Health has analyzed the preliminary data and makes the following recommendations:

1. Patient safety awareness

A major purpose of the Indiana Medical Error Reporting System is promoting awareness of patient safety. The topic of patient safety is often not included in formal educational programs for healthcare professionals. The Indiana Medical Error Reporting System initiative has prompted several health care facilities to hold a "Patient Safety Day" and provide educational opportunities on the topic. It is important that health care facilities and educational programs increase awareness of patient safety.

The Indiana State Department of Health encourages all health care facilities to promote patient safety awareness and recommends that all facility staff receive training on patient safety. If patient safety is a systemic problem, all facility staff needs to be aware of patient safety and their role in preventing medical errors. The Indiana State Department of Health recommends that all health care facilities have an active patient safety program that promotes patient safety issues for staff and patients.

The Indiana State Department of Health recommends that all health care facilities participate in regional and state-wide patient safety programs to improve coordination of patient care and the reduction of medical errors. Health provider organizations are encouraged to include patient safety in the educational activities and initiatives provided for members.

2. Study of Pressure Ulcer Events

The top reported event for 2006 was stage 3 or 4 pressure ulcers acquired after admission to the facility. This event was also the top reported event in Minnesota's reporting system. In 2006 the Centers for Medicare and Medicare Services established goals to reduce the rate of pressure ulcers in nursing homes. Because of the focus on pressure ulcers in nursing homes, there is an opportunity for collaboration on educational programs and initiatives to improve coordination of patient care.

The Indiana State Department of Health encourages academic programs and healthcare quality organizations to study the development of pressure ulcers in Indiana health care facilities and recommend protocols to promote the reduction of pressure ulcers.

3. Study of Foreign Objects Retained in a Patient after Surgery

The second most reported event for 2006 was the retention of foreign objects in a patient after surgery. Hospitals reported twenty-one (21) events where a foreign object was retained in a patient after surgery. Ambulatory surgery centers reported no events in that category. The discrepancy in reported events between the two types of facilities warrants further study to

determine why there are significant differences. It would be informative to know whether the differences are solely related to the type of surgeries performed at the facilities or whether there are differences in practices at the facilities.

The Indiana State Department of Health encourages academic programs and healthcare quality organizations to study the retention of foreign objects in a patient after surgery and recommend protocols to promote the reduction of retained foreign objects.

4. Study of Surgery on the Wrong Body Part Events

There were four surgery on the wrong body part events reported at hospitals and five reported at ambulatory surgery centers. Considering that ambulatory surgery centers perform only 28% of the surgical procedures, the rate for ambulatory surgery centers for this event is significantly higher than for hospitals. This warrants further study to determine why there are significant differences in the rates between the two types of facilities.

The Indiana State Department of Health encourages academic programs and healthcare quality organizations to study surgery on the wrong body part and recommend protocols to promote the reduction of surgery on the wrong body part events.

5. Distinguishing between Severity of Events

The Indiana Medical Error Reporting System requires health care facilities to report events in the twenty-seven (27) designated categories. Some of these categories only require reporting if the event results in death or serious disability. The reporting system does not distinguish between the two severity levels. Other states distinguish between the two severity levels. In order to improve the data collection, the Indiana State Department of Health will consider updating the reporting system to distinguish between events resulting in death and events resulting in serious disability.

6. Patient Safety Certification Program

The Indiana State Department of Health believes that the development of formal academic courses on healthcare quality and patient safety is a positive step towards increasing awareness of patient safety. These courses are generally a part of the curriculum for advanced degree programs. While these courses are extremely beneficial for students in those programs, they do not have the potential of reaching a wide range of healthcare professionals.

The Indiana State Department of Health encourages continuing studies programs of academic institutions and healthcare quality organizations to consider the development of continuing study programs directed at patient safety. A voluntary patient safety certification program could be developed similar to programs for project management and other continuing studies programs. The development of continuing studies programs could promote consistency between health care facilities and provide a forum for collaboration between facilities on patient safety issues.

7. Increased Partnership with Indiana Colleges and Universities

The development of solutions for patient safety issues requires the assistance of subject matter expertise. The Indiana State Department of Health does not have the subject matter expertise to address many of the patient safety issues. Like other medical care issues, patient safety requires an evidence-based approach to determine causes and effects and then apply that knowledge to the development of data-based solutions. Indiana colleges and universities are recognized leaders in healthcare education and research. The subject matter expertise of the educational institutions is needed to provide independent study and analysis of patient safety issues and the development of solutions. The Indiana State Department of Health encourages increased partnerships between Indiana colleges and universities and healthcare organizations on patient safety issues.

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ADDITIONAL INFORMATION ON MEDICAL ERRORS AND PATIENT SAFETY

There are numerous organizations that are a resource for information on patient safety. The following is a list of Web sites that provide information on patient safety. This list provides only a fraction of the resources available. There are many more resources available for consumers, health care providers, and policy makers.

Agency for Healthcare Policy and Research (AHRQ): www.ahrq.gov/consumer

The mission of the federal Agency for Healthcare Policy and Research is to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans. Information from this agency's research helps people make more informed decisions and improve the quality of healthcare services.

Centers for Medicare and Medicaid Services: www.cms.hhs.gov/quality

The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and works in partnership with the states to administer the Medicaid program. CMS has developed a number of quality improvement initiatives that can be found at this site.

Classifications of Patients: www.emergency-medicine.info/articles/asa-classification-grades.html

Classification of patients according to pre-operative physical status was initially suggested in 1941 by the American Society of Anesthetists, the forerunner of the American Society of Anesthesiologists (ASA). The modern classification system was adopted in 1961.

Consumers Advancing Patient Safety: www.patientsafety.org

Consumers Advancing Patient Safety is a consumer-led nonprofit organization, formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. In addition to the organization resources available on their Web site, this site also provides several links to other patient safety Web sites of interest to consumers.

Institute of Medicine of the National Academies: www.iom.edu

A nonprofit organization specifically created for science-based advice on matters of biomedical science, medicine, and health as well as an honorific membership organization, the Institute of Medicine was chartered in 1970 as a component of the National Academy of Sciences.

Institute for Safe Medication Practices: www.ismp.org/Pages/Consumer.html

Alerts for Patients page containing a listing of frequent medication errors and how to avoid them, general information and advice on medication safety for consumers.

Joint Commission on the Accreditation of Health Care Organizations (JCAHO):

www.jointcommission.org/PatientSafety/

The Commission evaluates and accredits more than 15,000 healthcare organizations and programs in the United States. Its mission is to continuously improve the safety and quality of care provided to the public. A number of patient safety tips for patients and consumers can be found at their website.

Leapfrog Group: www.leapfroggroup.org

The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. The Leapfrog Website provides quality and safety information about hospitals that consumers can search.

Minnesota Alliance for Patient Safety: www.mnpatientsafety.org

The Minnesota Alliance for Patient Safety was established in 2000 as a partnership between public and private health care organizations working together to improve patient safety. Information about Minnesota's patient safety coalition can be found at this site.

Minnesota Department of Health: www.health.state.mn.us/patientsafety/publications/index.html

This site provides information on Minnesota's Adverse Health Event Annual Reports.

National Academy for State Health Policy: www.nashp.org

The National Academy for State Health Policy is a non-profit, non-partisan organization dedicated to helping states achieve excellence in health policy and practice. The organization provides resources to compare patient safety initiatives and approaches across the states.

National Coordinating Council for Medication Error Reporting and Prevention: www.nccmerp.org

This organization is an independent body comprised of twenty-three national organizations. The mission of the National Coordinating Council for Medication Error Reporting and Prevention is to maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting and promotion of medication error prevention strategies.

National Patient Safety Foundation: www.npsf.org

The Foundation's mission is to improve the safety of patients through efforts to: identify and create a core body of knowledge; identify pathways to apply the knowledge; develop and enhance the culture of receptivity to patient safety; raise public awareness and foster communications about patient safety; and improve the status of the Foundation and its ability to meet its goals.

National Quality Forum: www.qualityforum.org

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national

consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

Pressure ulcer information

Mayo Clinic: www.mayoclinic.com/health/bedsores/DS00570

This site provides information from the Mayo Clinic, the world's first and largest integrated group medical practice.

Medline Plus: www.nlm.nih.gov/medlineplus/pressuresores.html

Medline Plus is a service of the U.S. National Library of Medicine and the National Institutes of Health

Protecting 5,000,000 Lives from Harm Campaign: www.ihl.org/IHI/Programs/Campaign

The Institute for Healthcare Improvement is a Cambridge, Massachusetts based not-for-profit organization. The Institute launched the Campaign to Protect 5 Million Lives from Harm, the next phase after their Campaign to Save 100,000 Lives.

Quality Interagency Coordination Task Force: www.quic.gov/report/

The Quality Interagency Coordination Task Force was established in 1998 in accordance with a Presidential directive. The purpose of the Task Force was to ensure that all federal agencies involved in purchasing, providing, studying, or regulating health care services were working in a coordinated manner toward the common goal of improving quality care.



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